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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PARTS 1301 and 1311

[Docket No. DEA-445N]

Program to Hire Special Assistant United States Attorneys in Targeted Federal Judicial Districts Utilizing Diversion Control Fee Account Funds

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing a rule that would expand and enhance the enforcement component of the Diversion Control Program (DCP) as previously outlined in the December 30, 1996, Federal Register document “Registration and Reregistration Application Fees,” hereinafter referred to as the 1996 Rule. The 1996 Rule specified six types of investigations involving the diversion of controlled substances, which could be pursued by the DCP utilizing funding from the Diversion Control Fee Account (DCFA). Those investigations included the theft or robbery of pharmaceutical controlled substances, the acquisition of pharmaceutical controlled substances through fraud or deceit, and other illegal diversion activities. The 1996 Rule also authorized the continued use and expansion by the DCP of Tactical Diversion Squads (TDSs), defined as, “enforcement teams consisting of Federal, state, and local law enforcement personnel fully dedicated to the investigation and prosecution of persons involved in the diversion of controlled substances.”

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-445N” on all correspondence, including any attachments.

The Drug Enforcement Administration encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

This proposed rule would expand on the already-recognized investigative activities funded by the DCFA and allow for the hiring of attorneys in support of these activities. The attorneys, hired by DEA and paid with funds from the DCFA, will be detailed to the Department of Justice (DOJ) as Special Assistant United States Attorneys (SAUSAs), and will assist in the investigation and prosecution of those diversion crimes outlined in the 1996 Rule, and related civil actions. DCFA-funded SAUSAs in the program would be exclusively engaged in duties which provide investigative and prosecutorial support to federal criminal and related civil diversion investigations conducted by the DEA and its partnering law enforcement agencies. The investigations, and the companion support provided by the attorneys detailed as SAUSAs in this program, will adhere to the guidelines for the use of DCFA funding found in Title 21, United States Code, 821, 822, and 886a; the 1996 Rule, 76 FR 39318, July 6, 2011; and 77 FR 15234, March 15, 2012.

In addition, the proposed rule would authorize the SAUSAs hired by DEA and detailed to DOJ to prosecute crimes that are derivative or ancillary criminal violations to the diversion crimes outlined in the 1996 Rule. Examples of these ancillary or derivative crimes would include money laundering or other financial crimes involving the proceeds of diversion activity; firearms and crimes of violence related to or caused by diversion activity; use of a communication facility to commit diversion crimes; and the forfeiture of assets which facilitate or are derived from diversion activity.

In addition to protecting the public, the proposed rule will enhance the protections provided to the DEA registrant community by the DCP by ensuring that those engaged in criminal and related civil violations affecting the DEA registrant population are apprehended,

and, equally as important, prosecuted. The proposed rule will ensure that illegal activities that endanger the safety of registrants and their employees (burglary and robbery of registered locations); threatens the credibility and financial stability of registrants and their employees (prescription forgery, fraud, and theft); and damages the public perception and reputation of the registrant community (prescribing or dispensing outside the course of medical practice and other offenses committed by registrants) will be fully addressed through robust investigation and prosecution.

The proposed rule is a continuation of the concepts outlined in “Controlled Substances and List 1 Chemical Registration and Reregistration Fees,” 77 FR 15234 (Mar. 15, 2012), hereinafter referred to as the 2012 Rule. The 2012 Rule provides that “it is essential to utilize a diverse skilled workforce and constantly review and modify all aspects of the DCP to help successfully execute the drug trafficking disruption goals of the National Drug Control Strategy and effectively prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of these substances for legitimate medical purposes.” It is in furtherance of that constant review – and modification when necessary – that this rule is proposed.

This proposed rule does not request an increase in Registration and Reregistration Fees.

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address,

etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) or confidential business information included in the text of your electronic submission that is not identified as directed above as confidential.

Legal Authority/Diversion Control Fee Account

Through the enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (CSA), Congress has established a closed system of distribution making it unlawful to handle any controlled substance or listed chemical except in a manner authorized

by the CSA. In order to maintain this closed system of distribution, the CSA imposes registration requirements on some handlers of controlled substances and list I chemicals.¹ 21 U.S.C. 822 and 957; 21 CFR 1301.13 and 1309.25. Under the CSA, the DEA is authorized to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals.² 21 U.S.C. 821 and 958(f). However, the DEA must set fees at a level that ensures the recovery of the full costs of operating the various aspects of its diversion control program as outlined in 21 U.S.C. 886a. This is known as the Diversion Control Fee Account (DCFA). The diversion control program consists of the controlled substance and chemical diversion control activities of the DEA which are related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals.³ 21 U.S.C. 886a(2). The DCFA is then utilized by the DEA in strict compliance with 21 U.S.C. 821, 822, and 886a; the 1996 Rule; 76 FR 39318, July 6, 2011; the 2012 Rule; as well as all applicable laws, regulations, and DEA policy to establish and implement the DEA registration process; to provide regulatory oversight of DEA registrants;

¹ Pursuant to the CSA, certain entities are exempted from registration, from paying the registration fee entirely, or are exempted from the requirement of a separate registration for activities performed as a coincident activity under a registered business activity.

² The Attorney General delegated authorities under the CSA (found in titles II and III of the Act) to the Administrator of the DEA, who in turn redelegated many of these authorities to the Assistant Administrator of the DEA Diversion Control Division. 28 CFR 0.100 *et seq.*

³ The Diversion Control Division is the strategic focus area within the Administration that carries out the mandates of the CSA to ensure that adequate supplies of controlled substances and listed chemicals are available to meet legitimate domestic medical, scientific, industrial, and export needs. The Diversion Control Division carries out the mission of the DEA to prevent, detect, and eliminate the diversion of these substances into the illicit drug market. Activities in support of the Diversion Control Division and its mission include: determination of program priorities; field management oversight; coordination of major investigations; drafting and promulgating regulations; the design and proposal of national legislation; advice and leadership on State legislation/regulatory initiatives; oversight of the importation and exportation of tableting and encapsulating machines, controlled substances, and listed chemicals; establishment of national drug production quotas; activities related to drug scheduling and compliance with international treaty obligations; the design and execution of diplomatic missions; computerized monitoring and tracking of the distribution of certain controlled substances; planning and allocation of program resources; and liaison efforts with industry and their representative associations as well as to the DEA's regulatory and law enforcement counterparts at the federal, State, tribal, and local levels.

and to prevent, detect, and investigate diversion from the legal channels prescribed by law into illegal channels that violate the CSA.

The Tactical Diversion Squad Program

As part of the DCP, and pursuant to 21 U.S.C. 821 and 886a, and the 1996 Rule, DEA has created Tactical Diversion Squad (TDS) units staffed by DEA Special Agents, Diversion Investigators, Task Force Officers (TFOs)⁴ and Intelligence Analysts to work collaboratively to investigate the criminal and related civil aspects of the illegal diversion of controlled substances. These illegal practices are outlined in the 1996 Rule and include prescribing or dispensing of controlled substances outside the course of practice, the theft of controlled substances, pharmacy burglary and robbery, prescription forgery and fraud, distribution of diverted controlled substances, and other violations of Federal law related to the diversion of controlled substances. In response to growing drug-related threats, particularly the threats posed by opioid abuse, the DEA has continued to grow the TDS program. Currently, the DEA has staffed 79 TDS groups across the United States to attack the illegal diversion and trafficking of pharmaceuticals.

Of particular note, state and local law enforcement agencies have invested 283 of their officers to work as TFOs with the TDS Squads across the United States. These TFOs represent the growing understanding in the law enforcement community of the threat posed by the diversion of pharmaceutical drugs into our society. The TFOs represent a tremendous return on investment for the DCFA as the salaries for these officers are borne by their respective departments, with the DCFA reimbursing the departments for overtime expenses and providing the TFOs with vehicle expenses, travel expenses, and investigative expenses.

⁴ A TFO is a sworn officer of a state or local law enforcement agency seconded to DEA and credentialed by DEA as a Federal law enforcement officer.

These groups have been extremely effective in attacking the prescription drug diversion and abuse problem when allied with our critical prosecution partners within the various United States Attorney's Offices. As the TDS program continues to grow, it is critical that more resources, such as SAUSAs, are available to prosecute these cases when necessary.

The DEA's Special Assistant United States Attorney Pilot Program

The United States is currently in the midst of an epidemic of opioid abuse and overdose death. Drug overdose has overtaken deaths from firearms and automobile accidents as the leading cause of accidental or unintentional injury death in the United States.⁵ In 2014, according to the Centers for Disease Control, opioid overdoses killed 28,000 people in the United States, with more than half of those deaths caused by prescription opioids. Drug overdose death increased by 11.4% from 2014 to 2015 alone (52,404 deaths to 47,055 deaths).⁶ Since 1999, the amount of opioid pain medicine prescribed in the United States has quadrupled, with a corresponding rise in the number of deaths from prescription opioids. In addition to the direct harm caused by the abuse of opioid drugs diverted from legitimate use, it is clear that the use and abuse of prescription opioids is a gateway to the use of other illegal substances. For example, more than 80% of heroin users in the United States used prescription drugs as a gateway to their eventual use of heroin.

Additionally, in a 2012 study by the Substance Abuse and Mental Health Services Administration (SAMHSA) of emergency room visits for drug related overdose in young adults aged 18 to 25, more than 11% were admitted for misuse/abuse of benzodiazepines;

⁵ Centers for Disease Control 2014 Deaths, Final Data Report.

⁶ Centers for Disease Control, Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015.

more than were admitted for use of heroin (9.9%), cocaine (8.8%), or methamphetamine (5.6%).⁷

As indicated above, to answer this drug abuse epidemic, DEA has dedicated increasing resources to the DCP through the expansion of the TDS program, which has resulted in dramatic program growth over the past decade. In 2006, DEA had five TDS groups in operation with only 70 Special Agents dedicated to diversion investigations and funded by the DCFA. By 2016, the number of TDS groups had grown to 79, with 340 Special Agents dedicated to diversion investigations.

The prosecution of those responsible for, and engaged in, criminal and related civil diversion activity is integral to public safety. As the number of personnel dedicated to diversion investigations has increased, the arrests and potential defendants identified for prosecution have also increased. Should prosecutions not keep pace with these increased activities, the reduction of the diversion of controlled substances cannot be accomplished. To help ensure that the increased investment of DCFA resources into the investigation of diversion activity outlined in the 1996 Rule are fully realized with prosecution efforts, the DEA, in cooperation with the Executive Office for United States Attorneys (EOUSA)⁸ and the United States Attorneys' Offices, proposes to institute a program to hire attorneys with the requisite experience and education to serve as Special Assistant United States Attorneys (SAUSAs) in targeted federal judicial districts. Pursuant to 21 U.S.C. 821 and 886a, the 1996 Rule, and the 2012 Rule, the hiring, training, and activities of these attorneys will be funded by the DCFA. Once hired, these attorneys will be provided with additional specialized

⁷ Substance Abuse and Mental Health Services Administration December 2012 Report entitled Admissions Reporting Benzodiazepine and Narcotic Pain Reliever Abuse at Treatment Entry.

⁸ The Executive Office for United States Attorneys (EOUSA) is the Department of Justice component that provides administrative and policy oversight to the 94 Offices of the United States Attorney.

training under this program for prosecuting crimes resulting from DCFA-funded investigations. The criteria utilized in determining the appropriate geographic placement of detailed SAUSAs will be based on an examination of several factors in each district, including prescription drug abuse rates; drug overdose death rates; an analysis of opioid prescribing and ordering; input from other Federal, state, and local officials; the number of DCFA-funded DEA personnel in the district; and the input from the United States Attorney, the Diversion Control Division, and the DEA Special Agent in Charge for each judicial district.

DEA proposes that the attorneys hired as a part of this program will be directly employed by DEA, and funded through the DCFA. Once hired, they would be detailed to DOJ and receive authorization to serve as SAUSAs from EOUSA, the United States Attorney, and the U.S. District Court in the district of hire to serve in the capacity of a SAUSA. In this role, the SAUSAs would be permitted to represent the United States in criminal and civil proceedings before the courts and apply for various legal orders. All of the anticipated activities will relate to, and result from, those investigations conducted pursuant to the 1996 Rule.

While the use of DEA attorneys detailed as SAUSAs and funded through the DCFA is a new concept, the use of attorneys detailed as SAUSAs to complement the capabilities of the United States Attorneys' Offices is not. Applicable Department of Justice policy states the following regarding SAUSAs employed by other agencies:

Attorneys employed in other departments or agencies of the federal government may be appointed as Special Assistants to United States Attorneys, without compensation other than that paid by their own agency, to assist in the trial or presentation of cases when their services and assistance are needed. Such appointments, and appointments of Assistant United States

Attorneys from one United States Attorney's office to another, may be made by the United States Attorney requiring their services.⁹

In many areas, SAUSAs have been designated from state and local prosecutors' offices to allow a greater volume of specific types of cases (firearms cases primarily) to be presented in federal court than would otherwise be possible with the resources allocated to the United States Attorneys' Office. Likewise, funds from the Federal High Intensity Drug Trafficking Area (HIDTA) grant program have been utilized to hire attorneys to serve as SAUSAs that specifically provide prosecutorial and legal services to narcotics task forces funded by the HIDTA program. Both of these programs have been highly effective and serve as good models for the proposed use of DCFA-funded SAUSAs to prosecute diversion-related offenses.

The goal of this proposed effort is to ensure the effective and efficient use of DCFA resources dedicated to the TDS program by providing resources to help ensure that criminal and related civil cases with sufficient evidence are prosecuted in a timely manner. All DCFA-funded SAUSAs in the program would be utilized exclusively to support DCFA-funded investigations conducted by the DEA and its partnering law enforcement agencies. The types of investigations in which the SAUSAs will assist, and the crimes they will prosecute will stem from the types of investigations identified in the 1996 Rule, which states: "The targets and types of investigations conducted by the DCP pursuant to 21 U.S.C. 821 are identified below.

(1) Registrants and their agents or employees suspected of diverting controlled substances from legitimate channels;

⁹ U.S. DEP'T OF JUSTICE, UNITED STATES ATTORNEYS' MANUAL, § 3-2.300 (1998), available at <https://www.justice.gov/usam/usam-3-2000-united-states-attorneys-ausas-special-assistants-and-agac>.

- (2) Persons who engage in the smuggling, theft, robbery and/or trafficking of pharmaceutical controlled substances, including, where appropriate, identifying and immobilizing their sources of supply, whether domestic or foreign, through enforcement of the controls relating to the manufacture, distribution, import, export, and dispensing of controlled substances;
- (3) Persons, both registered and nonregistered, who conduct controlled substances activities for which they do not have the required DOA or state authorization;
- (4) Persons who obtain pharmaceutical controlled substances from registrants through fraud, deceit, or circumvention of the controls on manufacturing, distribution, or dispensing, i.e. fraudulent use of another person's DEA registration number to obtain controlled substances, doctor shoppers, prescription forgers, etc.;
- (5) The trafficking by non-registrants in controlled substances which are fraudulently promoted as legitimate therapies (such as "herbal remedies" sold "under the counter" which actually contain a controlled substance);
- (6) Persons who use their DEA registrations to assist in the diversion or misuse of controlled substances for other than medical purposes, such as health care fraud, self-abuse, trading controlled substances for non-medical purposes, etc." 61 FR 68629.

During the course of the investigations described in paragraphs 1 through 6 of the 1996 Rule, additional criminal activity may be uncovered. To the extent this additional criminal activity is committed by an individual or group of individuals whose primary criminal activity is described in paragraphs 1 through 6 of the 1996 Rule, and the additional criminal activity is derivative of, or ancillary to, the illegal activity described in those paragraphs, the investigations have included this additional criminal activity, and these crimes will be prosecuted by the SAUSAs described in this proposed rule. Examples of this type of

additional criminal activity would include weapons offenses or crimes of violence in support of diversion offenses; money laundering, structuring or other financial violation to support diversion offenses, or utilizing monies derived from diversion offenses; the use of a telecommunication device in support of diversion offenses; and the forfeiture of assets derived from, or facilitating, diversion offenses.

Cost of the SAUSA Program

The DEA proposes to initially hire 20 attorneys utilizing funding from the DCFA to implement the program. The initial 20 attorneys would be selected to serve in a minimum of 12 and maximum of 20 federal judicial districts at an estimated annual cost of \$3.8 million.¹⁰ With an annual, Congressionally-approved budget of more than \$371,000,000.00 (Fiscal Year 2016), the expenditures related to the SAUSA program would comprise only 1% of the annual DCFA budget. As a result of the low cost in comparison to the overall DCFA budget, as well as the reprioritization of other DCFA expenditures, this project is not expected to result in an increase to the registration fee schedule. If finalized, this program would be continually evaluated by the DEA to ensure that DCFA funding is spent in accordance with guidelines for the use of DCFA funding found in 21 U.S.C. 821, 822, and 886a; the 1996 Rule; 76 FR 39318, July 6, 2011; and the 2012 Rule. DEA would also continuously evaluate the program to ensure that the project is successful in securing the criminal and civil prosecutions necessary to justify the continued expenditure of DCFA funding.

Regulatory Analyses

¹⁰ The cost estimate for the 20 positions is based on the U.S. Office of Personnel Management 2016 General Schedule (GS) Locality Pay Table for “Washington-Baltimore-Arlington, DC-MD-VA-WV-PA” at the GS-15 Step 5 level of \$145,162. The “Washington-Baltimore-Arlington, DC-MD-VA-WV-PA” is used to be conservative. Including an estimated 30% for benefits, the estimated cost per position is \$188,711 per year, or \$3,774,212 (\$3.8 million) per year for all 20 positions.

Executive Orders 12866 and 13563

This proposed rule was developed in accordance with the principles of Executive Orders 12866 and 13563. As described previously, the estimated annual cost of \$3.8 million is less than 1% of the annual DCFA budget and sufficient funding exists in the DCFA budget to allow for this program due to the reprioritization of other budgetary items within the DCP. This program will result in a net zero economic effect and no impact on registration fees. Therefore, the DEA does not anticipate that this rulemaking will have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

This proposed rule is not a "significant regulatory action" under Executive Order 12866 Section 3(f).

Executive Order 12988

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Unfunded Mandates Reform Act

This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule and by approving it certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. There are nearly 1.7 million DEA registrations, of which, a large majority either are held by small entities or are those employed by small entities. As discussed above, the DEA estimates the estimated annual cost of \$3.8 million is offset by reprioritization of other DCFA expenditures, resulting in a net zero economic effect and no impact on registration fees for any registrants. Therefore, the DEA estimates that the rule will not, if promulgated, have a significant effect on a substantial number of these small entities.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521

Dated: March 11, 2017

Chuck Rosenberg,
Acting Administrator.

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